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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,513	03/31/2004	Ed Van Breen	5838/2002	9910

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EXAMINER	
WESTERBERG, NISSA M	

ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/816,513	BREEN, ED VAN	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 2, 6, 8 - 16, 30 - 35, 39, 40, 42 - 44, 48* is/are pending in the application.

4a) Of the above claim(s) *8,10,11 and 15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 6, 8, 9, 12 - 14, 16, 30 - 35, 39, 40, 42 - 44, 48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed January 21, 2009, have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections constitute the complete set presently being applied to the instant application.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1, 6, 9 and 14 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 49 and 67 – 73 of copending Application No. 11/529096 in view of Murthy et al. (WO 01/107010). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed August 12, 2008 and those set forth below.

Applicant postpones action in regards to this rejection until they are notified of otherwise allowable subject matter. Therefore, this rejection is maintained for the reasons of record set forth in the Office Action mailed August 12, 2008.

Claim Rejections - 35 USC § 112 – 1st Paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

> art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. Applicant has amended claim 2 to recite that that "foam is generated in a device that does not contain a sponge" and cites p 11, ln 11 – 13 as supporting this amendment. This section states that "the cleanser of the composition of the present invention is not stored in direct contact with the applicator". P 6, ln 12 – 14 of the specification defines a "sponge" as an applicator which may induce foaming and/or used as an applicator for an eyelid cleanser. However this section of the specification only provides support for a claim in which the sponge is not in direct contact with the composition, not a device that does not contain a sponge. The Examiner was unable to locate an explicit mention of the use spongeless foam generating device in the specification. If such a device is used in the one of examples or elsewhere in the specification, Applicant is kindly requested to point by page and line number to where support can be found.

Claim Rejections - 35 USC § 112 – 2nd Paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. As amended, the Markush present for item (g) includes the items "methyl parabens, ethyl parabens and propyl parabens". Each of these is a specific chemical compound but the plural form used in the claim seems to indicate that each is a family of compounds with that name.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 2, 30 – 32, 39, 40 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Mundschenk et al. (US 5,665,332).

Mundschenk et al. discloses a foam comprising the anti-inflammatory agent freeze-dried aloe, water, methyl paraben and sodium lauryl sulfate (col 7, ln 65 – col 8, ln 2). When placed in a sponge-less foaming container, the composition produced a stable, readily broken foam capable of being applied to the skin (col 8, ln 5 – 9), which reads on a transiently stable foam.

"Effective for eyelid hygiene" is a recitation of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the

claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. As these compositions are useful for cleaning skin, there is no indication that these compositions are not capable of performing the function of eyelid hygiene.

The limitation is claim 2 regarding the sponge is a product-by-process limitation. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) **MPEP 2113**.

Many of the kit claims include a requirement for instructions. This limitation is not given patentable weight absent a new and unobvious functional relationship between the printed matter and the substrate. See *Lowry*, 32 F.3d at 1583-84, 32 USPQ2d at 1035; *In re Ngai*, 367 F.3d 1336, 70 USPQ2d 1862 (Fed. Cir. 2004).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 1, 6, 9, 12 – 14 and 16 were rejected under 35 U.S.C. 103(a) as being unpatentable over Niemiec et al. (EP 1060732) in view of Pugliese et al. (US 6,114,337), Malik et al. (WO 01/23517) and Simion (US 5,480,633). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed August 12, 2008 and those set forth below.

Applicant traverses this rejection on the grounds that Niemiec et al. fails to disclose the limitation of suitable for direct application to an eyelid of a subject and the instant specification indicates that the pH range of the composition is best kept about a inclusive range of 5.5 – 6.5. Niemiec et al. discloses vesicle systems having pH values as low as 4.0 ± 0.2 and lacks any teaching or suggestion as to how such compositions could be rendered suitable for direct application to an eyelid of a subject. None of the secondary references, Pugliese et al., Malik et al. or Simion, make up for the deficiencies of the primary reference. Pugliese et al. fails to disclose or suggest a controlled composition foam and fails to address how the skilled artisan might adapt the

disclosed anti-inflammatory compounds to render them suitable for direct application to an eyelid of a subject. Both Malik et al. and Simion fail to disclose or suggest a controlled composition foam suitable for direct application to an eyelid of a subject that comprises an anti-inflammatory agent.

These arguments are not found persuasive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The primary reference discloses a controlled composition form which includes an anti-inflammatory agent (¶ [0056]). The range pH values of the compositions prepared by Niemiec et al. ranges from 4.0 to 6.5, as in ¶ [0128]. Applicant has not provided any evidence that the pH values of the composition are unsuited for direct eyelid application, merely that a range of 5.5 to 6.5 is "best" Only claim 16 recites this range as being the required for the composition. "In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990) **MPEP 2144.05**

12. Claims 1, 2, 30 – 34, 39, 40, 42, 43 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mundschenk et al. (US 5,665,332) in view of Viola (US 3,962,150).

Mundschenk et al. discloses a foam comprising the anti-inflammatory agent freeze-dried aloe, water, methyl paraben and sodium lauryl sulfate (col 7, ln 65 – col 8, ln 2). When placed in a sponge-less foaming container, the composition produced a stable, readily broken foam capable of being applied to the skin (col 8, ln 5 – 9), which reads on a transiently stable foam.

Mundschenk et al. does not disclose the inclusion of applicator such as a sponge in a kit with the cleanser and dispenser.

Viola describes an aqueous skin cleansing composition suitable for use as a non-pressurized, aerated, low-density foam for use in personal care products (col 1, ln 5 – 10). The composition produces a relatively stable or collapsible foam, such as those that readily break or collapse under slight pressure (col 1, ln 63 – 68). The compositions are placed in a non-pressurized foam dispenser (a pre-measured amount) and foams are produced (col 7, ln 33 – 48 and the examples, such as col 8, ln 47 – 50). The compositions can be used in conjunction with an applicator such as facial or toilet tissue (col 6, ln 1 – 4). Applicant has defined sponge to include a "fiber applicator of any kind" (p 6 of the instant specification), encompassing facial and toilet tissue.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to prepare a kit comprising the anti-inflammatory containing cleanser of Mundschenk et al. with an applicator. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because Viola discloses that similar transiently stable foamed cleanser compositions can be used in conjunction with an applicator such as a sponge.

"Effective for eyelid hygiene" is a recitation of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. As these compositions are useful for cleaning skin, there is no indication that these compositions are not capable of performing the function of eyelid hygiene.

The limitation is claim 2 regarding the sponge is a product-by-process limitation. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) **MPEP 2113**.

Many of the kit claims include a requirement for instructions. This limitation is not given patentable weight absent a new and unobvious functional relationship between the printed matter and the substrate. See *Lowry*, 32 F.3d at 1583-84, 32 USPQ2d at 1035; *In re Ngai*, 367 F.3d 1336, 70 USPQ2d 1862 (Fed. Cir. 2004).

13. Claims 1, 2, 30 – 32, 35, 39, 40, 44 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mundschenk et al. (US 5,665,332) in view of Faryniarz et al. (US 5,429,815).

Mundschenk et al. discloses a foam comprising the anti-inflammatory agent freeze-dried aloe, water, methyl paraben and sodium lauryl sulfate (col 7, ln 65 – col 8, ln 2). When placed in a sponge-less foaming container, the composition produced a stable, readily broken foam capable of being applied to the skin (col 8, ln 5 – 9), which reads on a transiently stable foam.

Mundschenk et al. does not disclose the use of an airless foaming device as the dispenser.

Faryniarz et al. discloses a sprayable cosmetic product containing dialkyl ether/hydrocarbon as the propellant that upon activation of the spray nozzle, produces a thick, creamy mousse (foam; abstract). Therefore, these foams are generated using an airless foaming device, as dialkyl ether/hydrocarbon and not air is the gas used to generate the foam material.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to prepare to dispense the anti-inflammatory containing cleanser of Mundschenk et al. using an airless foaming device. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because Faryniarz et al. discloses that foams can be generated in the absence of air, such as through the use of dialkyl ether/hydrocarbon propellants .

"Effective for eyelid hygiene" is a recitation of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. As these compositions are useful for cleaning skin, there is no indication that these compositions are not capable of performing the function of eyelid hygiene.

The limitation is claim 2 regarding the sponge is a product-by-process limitation. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) **MPEP 2113**.

Many of the kit claims include a requirement for instructions. This limitation is not given patentable weight absent a new and unobvious functional relationship between the printed matter and the substrate. See *Lowry*, 32 F.3d at 1583-84, 32 USPQ2d at 1035; *In re Ngai*, 367 F.3d 1336, 70 USPQ2d 1862 (Fed. Cir. 2004).

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

NMW